

BEFORE THE BOARD OF ALTERNATIVE HEALTH CARE
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the proposed) NOTICE OF PUBLIC HEARING
amendment of ARM 24.111.301) ON PROPOSED AMENDMENT
definitions, ARM 24.111.511)
naturopathic physician natural)
substance formulary list,)
ARM 24.111.602 direct-entry)
midwife apprenticeship)
requirements, and ARM 24.111.613)
required reports)

TO: All Concerned Persons

1. On December 9, 2004, at 10:00 a.m., a public hearing will be held in room 438, Park Avenue Building, 301 South Park Avenue, Helena, Montana to consider the proposed amendment of the above-stated rules.

2. The Department of Labor and Industry (Department) will make reasonable accommodations for persons with disabilities who wish to participate in the public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the Board of Alternative Health Care (Board) no later than 5:00 p.m., on December 2, 2004, to advise us of the nature of the accommodation that you need. Please contact Cheryl Brandt, Board of Alternative Health Care, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2394; Montana Relay 1-800-253-4091; TDD (406) 444-2978; facsimile (406) 841-2343; e-mail dlibsdahc@state.mt.us.

3. The Board proposes to amend the following existing rules, deleted matter stricken, new matter underlined:

24.111.301 DEFINITIONS (1) "Direct supervision" means the physical presence of the licensed supervisor. Direct supervision is required for level I, II and III-A apprentices.

(1) remains the same but is renumbered (2).

~~(2) (3) "Indirect supervision" means the physical presence of the licensed supervisor is not always required. Indirect supervision may only be implemented during level III of the direct entry midwife apprenticeship, and at the discretion of the licensed supervisor. immediate availability of the licensed supervisor by telephone.~~

(3) remains the same but is renumbered (4).

~~(4) (5) "Personal supervision" means the physical presence of the licensed supervisor either direct or indirect supervision as required for direct-entry midwife apprenticeships.~~

AUTH: 37-1-131, 37-27-105, MCA
IMP: 37-27-205, 37-27-320, MCA

22-11/18/04

MAR Notice No. 24-111-18

REASON: It is reasonable and necessary to amend this rule to reconcile it and ARM 24.111.602 with the apprenticeship supervision requirements of 37-27-205, MCA. The proposed amendments do not change current supervision requirements for licensed apprentices but are proposed only to further define and clarify the levels of supervision and explain the relationship between personal supervision and direct supervision of apprentices. Authority cites are being amended for accuracy and to reflect the full statutory authority of the Board to promulgate rules.

24.111.511 NATUROPATHIC PHYSICIAN NATURAL SUBSTANCE FORMULARY LIST (1) through (2)(r) remain the same.

(s) tryptophan; and

(t) remains the same.

(3) Naturopathic physicians may prescribe and administer antimicrobials. Naturally derived examples are:

(a) antifungal agents: ~~_____nystatin (streptomyces noursei), griseofulvin, gentian violet;~~

(i) fluconazole;

(ii) gentian violet;

(iii) griseofulvin;

(iv) itraconazole;

(v) ketoconazole;

(vi) nystatin; and

(vii) terbinafine;

(b) ~~cephalexan, cefaclor _____ derived from penicillium species;~~ cephalosporin derivatives:

(i) cefaclor;

(ii) cefadroxil;

(iii) cefdinir;

(iv) cefixime;

(v) cefpodoxime;

(vi) cefprozil;

(vii) ceftibuten;

(viii) ceftriaxone;

(ix) cephradine; and

(x) loracarbef;

(c) erythromycin and its salts: ~~(streptomyces erythreus);~~

(i) azithromycin;

(ii) clarithromycin; and

(iii) nitromide;

(d) penicillins: ~~amoxicillin, ampicillin, penicillin G, penicillin VK, cloxacillin, dicloxacillin _____ all derived from penicillium species;~~

(i) amoxicillin;

(ii) amoxicillin clavulanate;

(iii) ampicillin;

(iv) cloxacillin;

(v) dicloxacillin;

(vi) penicillin G; and

(vii) penicillin VK;

(e) tetracyclines: ~~oxytetracycline, doxycycline,~~

~~minocycline, all derived from streptomyces species.~~

- (i) doxycycline;
- (ii) minocycline; and
- (iii) oxytetracycline;
- (f) nitrofurantoin derivatives:
- (i) nitrofurantoin;
- (g) sulfonamide derivatives:
- (i) sulfamethoxazole; and
- (ii) trimethoprim/sulfamethoxazole; and
- (h) fluoroquinolone derivatives:
- (i) ciprofloxacin;
- (ii) levofloxacin; and
- (iii) ofloxacin;

(4) through (5)(e) remain the same.

- (f) ephedra† :
- (i) ephedrine; and
- (ii) remains the same.
- (g) ergot† :
- (i) remains the same.
- (ii) ergotamine tartrate; and
- (iii) through (i) remain the same.
- (j) hyoscamus† :
- (i) remains the same.
- (ii) hyoscyamine; and
- (iii) through (l) remain the same.

(m) oxycodone;

(m) through (t) remain the same but are renumbered (n) through (u).

~~(u)~~ (v) viscum album† :

- (i) iscador; and
- (ii) iscucin; and
- (v) remains the same but is renumbered (w).
- (6) through (6)(c) remain the same.
- (d) saline solutions; and
- (e) through (7)(b) remain the same.
- (c) iodinated glycerol; and
- (d) through (8)(g) remain the same.
- (h) secretin; and

(h) remains the same but is renumbered (i).

(9) remains the same.

(10) Naturopathic physicians may prescribe and administer hormones. The following are examples:

(a) through (a)(ii) remain the same.

(iii) cortisone;

(iii) and (iv) remain the same but are renumbered (iv) and (v).

~~(v)~~ (vi) prgenenolone; and

(vi) remains the same but is renumbered (vii).

(b) and (c) remain the same.

(d) gonadal† :

(i) estrogens† :

(A) through (F) remain the same.

(G) mestranol; and

(H) remains the same.

- (ii) progesterones† :
- (A) and (B) remain the same.
- (C) progesterones; and
- (D) progestogens; and
- (iii) remains the same.
- (e) pituitary hormones† :
- (i) remains the same.
- (f) thymus; and
- (g) thyroid USP; ~~(Ex. armour thyroid), thyroglobulin USP~~
~~(Ex. prolloid), liothyronine, levothyroxine.~~
- (i) levothyroxine; and
- (ii) liothyronine;
- (h) thyroglobulin USP;
- (11) through (12)(e) remain the same.
- (f) iodine† :
- (i) potassium iodide; and
- (ii) through (i) remain the same.
- (j) silver nitrate; and
- (k) trace mineral compounds† :
- (i) through (iii) remain the same.
- (iv) vanadium; and
- (v) remains the same.
- (13) remains the same.
- (a) bile salts and acids† :
- (i) through (iv) remain the same.
- (v) ursodeoxycholic acid; and
- (vi) remains the same.
- (b) biological agents† :
- (i) urea; and
- (ii) remains the same.
- (c) digestive aides† :
- (i) betaine HCL; and
- (ii) and (d) remain the same.
- (e) misoprostol;
- (e) and (f) remain the same but are renumbered (f) and (g).
- ~~(g)~~ (h) salicylic acid; and
- (h) remains the same but is renumbered (i).
- (14) through (14)(b) remain the same.
- (c) cyanocobalamin (vitamin B₁₂)† :
- (i) through (e) remain the same.
- (f) pantothenic acid (vitamin B₅)† :
- (i) remains the same.
- (g) phosphatidylcholine;
- (g) through (i) remain the same but are renumbered (h) through (j).
- ~~(j)~~ (k) vitamin A† :
- (i) remains the same.
- ~~(k)~~ (l) vitamin D† :
- (i) and (ii) remain the same.
- (iii) dovonex; and
- (iv) remains the same.
- ~~(l)~~ (m) vitamin E; and
- ~~(m)~~ (n) vitamin K† :
- (i) remains the same.

- (15) through (15)(b) remain the same.
- (c) ~~rhogam~~ rh immune globulin; and
- (d) remains the same.
- (16) remains the same.
- (a) debridement/escharotic agents† :
 - (i) and (ii) remain the same.
 - (iii) urea cream 40%; and
 - (iv) remains the same.
- (b) miscellaneous topical agents† :
 - (i) selenium sulfide; and
 - (ii) through (d) remain the same.
- (e) topical antibiotics† :
 - (i) silver sulfadiazine cream; and
 - (ii) ~~bactroban~~† mupirocin;
- (f) topical and local anesthetics† :
 - (i) through (iii) remain the same.
 - (iv) lidocaine HCL; and
 - (v) and (17) remain the same.

AUTH: 37-1-131, 37-26-201, MCA

IMP: 37-26-301, MCA

REASON: It is reasonable and necessary to amend this rule because the natural substance formulary list created pursuant to 37-26-201(9), MCA, must be reviewed at least annually by the formulary committee pursuant to 37-26-301(3), MCA. That committee met to update the formulary list within the parameters of the law and recommended to the Board that the rule be amended accordingly. In addition, the licensed pharmacist member of the committee requested that the Board update the formulary list at this time as it serves as a resource to pharmacists and facilitates their ability to fill prescriptions written by naturopathic physicians. It is also necessary to replace trade names with proper substance names and to rearrange the formulary list using proper formatting protocols. The deletion of natural substances in this proposed amendment is not intended to reflect a withdrawal of authority for naturopaths to prescribe those substances. Rather, any deletions reflect either the substitution of natural substances for the corresponding trade names or the elimination of unnecessary and superfluous examples encompassed by other items in the list. Authority cites are being amended for accuracy and to reflect the full statutory authority of the Board to promulgate rules.

24.111.602 DIRECT-ENTRY MIDWIFE APPRENTICESHIP REQUIREMENTS (1) The terms "direct supervision", "indirect supervision", and "personal supervision" used herein are defined in ARM 24.111.301.

~~(1) (2) The direct-entry midwife apprenticeship license program shall be that instructional period composed of practical experience time obtained under the personal supervision of a supervisor approved by the board. A direct-entry midwife apprentice shall not work alone, except at the discretion of the licensed supervisor under level III as defined below.~~

(2) and (2)(a) remain the same but are renumbered (3) and (3)(a).

(b) ~~agreement of parties that supervisor will provide personal supervision of the direct entry midwife apprentice during levels I and II, and may, at the supervisor's discretion, allow the direct entry midwife apprentice to work under indirect supervision during level III only;~~ supervision shall be provided which is consistent with these rules; and

(c) remains the same.

~~(3)~~ (4) A level I direct-entry midwife apprenticeship is served under the ~~personal~~ direct supervision of the licensed supervisor, with a focus on prenatal care. To complete level I, the direct-entry midwife apprentice shall:

(a) through (d) remain the same.

~~(4)~~ (5) A level II direct-entry midwife apprenticeship is served under the ~~personal~~ direct supervision of the licensed supervisor, with a focus on birth, postpartum and newborn care. To complete level II, the direct-entry midwife apprentice shall:

(a) through (e) remain the same.

~~(5)~~ (6) A level III direct-entry midwife apprenticeship is served as either level III-A or III-B, as defined below, ~~under the personal supervision of the licensed supervisor or as level III B, as defined below, under indirect supervision.~~ The focus of level III shall be continuous prenatal, perinatal and postnatal care. To complete level III, the direct-entry midwife apprentice shall:

(a) through (e) remain the same.

~~(6)~~ (7) Level III direct-entry midwife apprentices are separated as follows:

(a) A level III-A direct-entry midwife apprentice shall require ~~personal~~ direct supervision ~~in the form of the physical presence of~~ by the licensed supervisor;

(b) A level III-B direct-entry midwife apprentice shall require ~~indirect~~ direct supervision ~~in that the physical presence of the licensed supervisor is not always required. Level III B may only be implemented upon prior board approval by the licensed supervisor unless, in the professional judgment of the supervisor, with concurrence of the board, the level III-B apprentice is capable of safely and competently performing midwifery services under indirect supervision~~ after the following requirements have been met:

(i) verification of completion of 10 ~~personally~~ directly supervised continuous care births, as required by ARM 24.111.604;

(ii) remains the same.

(iii) a formal outline of the method of indirect supervision communication shall be submitted in writing to the board for approval, which shall include supervisor chart review and ~~may include~~ telephone contact supervision.

(7) remains the same but is renumbered (8).

~~(8)~~ (9) To be approved by the board as a supervisor of a direct-entry midwife apprentice, each supervisor shall:

(a) remains the same.

(i) A licensed direct-entry midwife supervisor shall have

~~been licensed for one year and have~~ 20 post-licensure continuous care births as primary attendant before becoming a supervisor for level II and III apprentices, except for those licensees who have successfully passed the first licensing exam administered by the board.

(ii) A licensed direct-entry midwife who has not ~~been licensed for one year and/or~~ completed 20 post-licensure continuous care births may only supervise level I apprentices;

(b) and (c) remain the same.

(d) notify the board in writing of any change in the supervisory relationship, including advancement from ~~personal~~ direct to indirect supervision, termination of the supervisory relationship or any other relevant changes and submit supervision change notification to the board so that it is received on or before the day that supervised tasks are performed in order for them to count toward licensure requirements; and

(e) be directly responsible for all activities undertaken by the apprentice(s) under their supervision agreement.

(10) Violation of the board statutes or rules may result in license discipline action against the direct-entry midwife apprentice, or supervisor, or both.

AUTH: 37-1-131, 37-27-105, MCA

IMP: 37-27-105, 37-27-201, 37-27-205, 37-27-321, MCA

REASON: It is reasonable and necessary to amend this rule to reconcile it and ARM 24.111.301 with the apprenticeship supervision requirements of 37-27-205, MCA. The proposed amendments do not change current levels of supervision required for licensed apprentices but are proposed only to further define and clarify the levels of supervision and explain the relationship between personal supervision and direct supervision of apprentices.

It is reasonable and necessary to amend ARM 24.111.602(8) [to be renumbered (9)] relating to qualification of direct-entry midwife apprentice supervisors. The Board determined that it is not necessary for the public's protection for a direct-entry midwife to be licensed for one year before becoming a supervisor for Level II and III apprentices so long as the supervisor has 20 continuous care births as the primary attendant before supervising apprentices at those levels. It is also reasonable and necessary to clarify that the 20 continuous care births as a primary attendant must be post-licensure and cannot include births attended during an apprenticeship or any other setting in which the supervisor applicant was supervised. Proposed new section (10) was previously included in (9)(e) and has been separated to comply with proper formatting guidelines. The proposed amendments will have no fiscal impact. Authority cites are being amended for accuracy and to reflect the full statutory authority of the Board to promulgate rules.

24.111.613 REQUIRED REPORTS (1) A licensed direct-entry

midwife shall submit semiannual summary reports on each client, covering the six-month period of January 1 through July 1, or July 1 through January 1 as appropriate, as required by 37-27-320, MCA. The reports are due on or before January 15 and July 15 of each year.

(a) If a licensed direct-entry midwife does not have any clients during a reporting period, the licensee shall notify the board in writing by the reporting date.

(2) remains the same.

(a) A level III-B apprentice direct-entry midwife, approved by the board for indirect supervision, shall be responsible for filing the statutorily required 72 hour mortality/morbidity report and the semiannual summary report.

(b) If a level III-B direct-entry midwife apprentice does not have any clients during a reporting period, the apprentice shall notify the board in writing by the reporting date.

(b) remains the same but is renumbered (c).

AUTH: 37-1-131, 37-27-105, MCA

IMP: 37-27-320, MCA

REASON: It is reasonable and necessary to amend this rule to require that direct-entry midwives and apprentices shall notify the Board in writing by the required reporting dates if there were no patients for whom care was provided during the reporting period. In the past, the Board or staff had to make affirmative inquiry of licensees to determine either noncompliance with the reporting requirements or that the licensees failed to submit a report because they had no patients on which to report. This amendment shifts the responsibility to licensees to inform the Board of their compliance with the reporting requirements. The proposed amendment has no fiscal impact. Authority cites are being amended for accuracy and to reflect the full statutory authority of the Board to promulgate rules.

4. Concerned persons may present their data, views or arguments either orally or in writing at the hearing. Written data, views or arguments may also be submitted to the Board of Alternative Health Care, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2343, or by e-mail to dlibsdahc@state.mt.us, and must be received no later than 5:00 p.m., December 17, 2004.

5. An electronic copy of this Notice of Public Hearing is available through the Department and Board's site on the World Wide Web at <http://discoveringmontana.com/dli/ahc>. The Department strives to make the electronic copy of this Notice of Public Hearing conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered. In addition, although the Department strives to keep its website accessible at all times, concerned persons

should be aware that the website may be unavailable during some periods, due to system maintenance or technical problems, and that a person's technical difficulties in accessing or posting to the e-mail address do not excuse late submission of comments.

6. The Board of Alternative Health Care maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this Board. Persons who wish to have their name added to the list shall make a written request, which includes the name and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding all Board of Alternative Health Care administrative rulemaking proceedings or other administrative proceedings. Such written request may be mailed or delivered to the Board of Alternative Health Care, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, faxed to the office at (406) 841-2343, e-mailed to dlibsdahc@state.mt.us, or may be made by completing a request form at any rules hearing held by the agency.

7. The bill sponsor notice requirements of 2-4-302, MCA, do not apply.

8. Lorraine Schneider, attorney, has been designated to preside over and conduct this hearing.

BOARD OF ALTERNATIVE HEALTH CARE
DOLLY BROWDER, LM, Chairman

/s/ WENDY J. KEATING
Wendy J. Keating, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

/s/ DARCEE L. MOE
Darcee L. Moe
Alternate Rule Reviewer

Certified to the Secretary of State November 8, 2004